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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,559	06/30/2003	Andrew D. Murdin	032931-0264	7270

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,559	MURDIN ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 6/30/04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 8-11,26-28,35 and 39-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-11,26-28,35 and 39-46 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 6/30/04 is made. Claims 8-11, 26-28, 35 and 39-46 are currently pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-11, 26-28, 35 and 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to vaccine vectors and pharmaceutical compositions comprising a nucleic acid molecule which includes SEQ ID NO:2, 4, or 6 and, optionally a pharmaceutically acceptable carrier or diluent and methods of treating or preventing C.pneumoniae infection through the administration of the vaccine vectors or pharmaceutical compositions. These claims and methods read on 'naked' DNA vaccines and do not require the use of a recombinant host cell for expressing the vector or DNA inside the host. The specification fails to enable the use of

immunogenic/pharmaceutical compositions/vaccines comprising solely the isolated nucleic acid encoding SEQ ID NO:2, 4 or 6, or immunogenic/pharmaceutical compositions/vaccines comprising the isolated nucleic acid encoding SEQ ID NO:2, 4 or 6 linked to a promoter. The specification fails to provide adequate guidance regarding how one would prepare a nucleic acid which when introduced into a host would induce an immune response against the protein encoded by said nucleic acid. In contrast to direct protein immunogens, nucleic acids are required to target appropriate cell types within a host, become transcriptionally active, appropriately process any encoded proteins and present such proteins to the host in a manner suitable for recognition by the host's immune system. Such a "gene therapy" approach to epitope delivery suffers from all of the limitations associated with gene therapy technology. It is unclear if Applicants intend to claim recombinant host cells as vaccines, as opposed to the naked DNA vaccines/compositions currently claimed. The latter are not enabled as it would take undue experimentation on the part of the skilled artisan to determine how to get a non-immunogenic isolated DNA molecule to produce a protective or therapeutic immune response. It is suggested that Applicants amend the claims reciting "vaccine vectors" to "expression vectors" and that the compositions claiming naked DNA to recombinant microorganisms transformed with the expression vectors.

Claim Rejections - 35 USC § 112

3. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is indefinite because of the recitation "optionally". It is generally viewed that if an ingredient is optional, it does not belong in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-11, 35 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalman et al (Nat. Genet. April 1999. 62(3): 880-886) in view of Griffais (US 6,559,294 B1).

Kalman et al teach the complete genome of C.pneumoniae. Kalman et al teach the nucleotide coding sequence and the deduced amino acid sequence of a 76kDa C.pneumoniae protein which they have identified as a 'conserved' protein. This protein is 100% identical to Applicant's SEQ ID NOs: 2 and 6, as well as a nucleic acid which is a 100% match to SEQ ID NO: 1. Although Kalman et al do not specifically teach an expression vector comprising the isolated nucleotide sequence encoding SEQ ID NO:2, 4 or 6 linked to a promoter for expression of the polypeptide, it would have been prima facie obvious to one of ordinary skill in the art to operatively link said nucleotide sequence to a promoter for expression of the polypeptide in a host cell (mammalian or bacterial) in order to produce a polypeptide and to make antibodies for detection of the

C.pneumoniae pathogen. Griffais et al teach the recombinant production of polypeptides identified through analysis of the C.pneumoniae genome and teach that these polypeptides may be used in detection methods or to generate antibodies. Promoters and other elements necessary to allow the expression and/or the secretion of the nucleotides sequences in a given host cell are specifically taught. See Column 46, lines 14-25. Griffais specifically teaches the use of mammalian host cells (see column 46, lines 14-25), as well as the use of CMV as a promoter (column 46, line 45), and they both would have been obvious choices to those of ordinary skill in the art at the time the invention was made when making the recombinant proteins. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to recombinantly produce the antigen identified by Kalman et al specifically because Kalman has identified the protein as a conserved protein and it would be useful in detection of C.pneumoniae and because the prior art, as demonstrated by Griffais, teach that doing so was routine in the art.

The terms "pharmaceutical composition" and "vaccine" are intended uses only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "physiologically acceptable carrier" reads on water and therefore would be inherent in the preparation of the vectors. Although the teachings of Kalman and Griffais et al do not specifically recite the expression plasmids pCACPNM555a, pCAI555 or pCAD76kDa, the structure of

these plasmids is taught by the combined teachings of Kalman and Griffais et al and therefore would be identical to that of pCACPNM555a, pCAI555 or pCAD76kDa, absent evidence to the contrary.

Response to Applicants' Arguments:

Applicants argue that Kalman does not disclose how to use any of their DNA sequences as a DNA-based vaccine. They also argue that the DNA of Kalman is incapable of being expressed as is required in a DNA-based vaccine. They also argue that there is no suggestion in Griffais to use any of Kalman's sequences as a DNA-based vaccine, let alone the particular coding sequence for the 76kDA protein. Lastly, Applicants argue that identifying a suitable C.pneumoniae sequence for use in a vaccine is no easy matter an only a few of the opening reading frames of the C.pneumoniae genome can be used as vaccines. A 1.132 Declaration by inventor Andrew Murdin was submitted to show that only 8 of the 36 ORFs in their C.pneumoniae vaccine program provided a protective effect.

These arguments and Declaration have been fully and carefully considered, however, they are not deemed persuasive in overcoming the rejection. Kalman et al. teach the nucleotide coding sequence and the deduced amino acid sequence of a 76kDa C.pneumoniae protein. This protein is 100% identical to Applicant's SEQ ID NOs: 2 and 6, as well as a nucleic acid which is a 100% match to SEQ ID NO: 1. Kalman teaches that it is a conserved protein. See attached sequence alignments which should have been mailed with the first Office Action. Griffais is merely cited to demonstrate that the use of the recombinant production of polypeptides identified

through analysis of the C.pneumoniae genome and teach that these polypeptides may be used in detection methods or to generate antibodies. Promoters and other elements necessary to allow the expression and/or the secretion of the nucleotides sequences in a given host cell are specifically taught. See Column 46, lines 14-25. Griffais specifically teaches the use of mammalian host cells (see column 46, lines 14-25), as well as the use of CMV as a promoter (column 46, line 45), and they both would have been obvious choices to those of ordinary skill in the art at the time the invention was made when making the recombinant proteins. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Kalman teaches the identical nucleic acid and protein sequences as those disclosed by Applicant and even teaches that these proteins are conserved proteins. Accordingly, the production of expression vectors and transformed host cells comprising these nucleic acid sequences which have been taught to encode a conserved 76kDa protein would have been obvious to one of ordinary skill in the art so that they could be used in diagnostic assays or methods of inducing an immune response.

With respect to Applicants' argument that it would not have been obvious to use these sequences as vaccines, the terms "pharmaceutical composition" and "vaccine" are intended uses only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order

to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "physiologically acceptable carrier" reads on water and therefore would be inherent in the preparation of the vectors. The expression vectors which would have been obvious based on the combined teachings of Kalman and Griffais are structurally identical to the claimed compositions. Although the teachings of Kalman and Griffais et al do not specifically recite the expression plasmids pCACPNM555a, pCAI555 or pCAD76kDa, the structure of these plasmids is taught by the combined teachings of Kalman and Griffais et al and therefore would be identical to that of pCACPNM555a, pCAI555 or pCAD76kDa, absent evidence to the contrary.

A patent cannot be granted to a known compound/molecule. However, a new method of using a known compound may be patentable.

6. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

JENNIFER E. GRASER
PRIMARY EXAMINER

9/2/04